UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 12, 2007

MEMORANDUM

SUBJECT: Review of "*Determination of Removal Efficiency of Permethrin (PER) and Piperonyl Butoxide (PBO) from Hand Surfaces Using Isopropyl Alcohol Dressing Sponges*"

FROM: Charles Smith, Environmental Scientist/Risk Assessor
Reregistration Branch 2
Health Effects Division (7509P)

THRU: Jeff Evans, Biologist
Chemistry Exposure Branch
Health Effects Division (7509P)

TO: Cathryn O'Connell
Special Review and Reregistration Division (7508P)

DP Barcode: 336766
PC Code: 109701 and 067501
MRID Number: 461886-24

Attached is a review of the MRID 461886-24 "*Determination of Removal Efficiency of Permethrin (PER) and Piperonyl Butoxide (PBO) from Hand Surfaces Using Isopropyl Alcohol Dressing Sponges*" submitted by the Non-Dietary Exposure Task Force. The purpose of the study was to measure the total amount of permethrin and piperonyl butoxide residues that can be removed from the hand surface following application of a measured amount of a standard formulation to the hand.

Five test subjects participated in this study. The formulated product was diluted in isopropyl alcohol and 25 uL was applied directly to the washed hands of the test subjects and allowed to dry for 30 minutes. Following the drying time, the hands of the subjects were then wiped with two dressing sponges wetted with isopropyl alcohol (IPA) to determine the removal efficiency of three concentrations of PER (0.771% ai) and PBO (0.741% ai) from the hand.

The total amount of residue removed from the participants hands by IPA were calculated by the study author for each hand of the test subjects. Residues were reported for PER and PBO at three different application rates. Nominal concentrations of 1.97 ug, 18.8 ug, and 59.2 ug PER and associated concentrations of 1.72 ug, 16.9 ug and 56.0 ug of PBO were applied to the hands. Average PER residues removed from the test subjects' hands were 1.57 ug (79.7% of the applied), 17.4 ug (92.7% of the applied), and 52.7 ug (89.0% of the applied). Average PBO residues removed from the test subjects' hands were 1.61 ug (93.7% of the applied), 16.3 ug (96.3% of the applied), and 49.5 ug (88.4% of the applied). The overall average recoveries were 87.1 ± 7.2% for PER and 92.8 ± 10.3% for PBO.

The primary review for this study was conducted by Versar, Inc. A secondary review was conducted by the Health Effects Division (HED). The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines were used to review the study. Overall, both the performance of this study and the data generated in this study conformed to the criteria set forth in the protocol and guidelines. HED believes the data within this study is of high quality and valid for risk assessment purposes.

Versar inc.

MEMORANDUM

TO: Margarita Collantes cc: 110082.4000.001.01

FROM: Traci Brody/Linda Phillips

DATE: April 7, 2004

SUBJECT: Review of "*Determination of Removal Efficiency of Permethrin (PER) and Piperonyl Butoxide (PBO) from Hand Surfaces Using Isopropyl Alcohol Dressing Sponges*" (Project #: 01-013-PY01)

This report reviews a study entitled "*Determination of Removal Efficiency of Permethrin (PER) and Piperonyl Butoxide (PBO) from Hand Surfaces Using Isopropyl Alcohol Dressing Sponges.*" The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines were used to review the study.

Reviewers: Traci Brody/Linda Phillips **Date: April 7, 2004**

STUDY TYPE: Active Transfer; Hand

TEST MATERIAL: The test substance was a pre-fill emulsion similar to that of an indoor fogger formulation developed by the McLaughlin Gormley King Company (MGK) containing the active ingredients: Permethrin (0.771% ai wt/wt) and Piperonyl Butoxide (0.741% ai wt/wt).

SYNONYMS: Permethrin = PER
Piperonyl Butoxide = PBO

CITATION:

Study Director/Author:	Sami Selim, Ph.D.
Title:	*Determination of Removal Efficiency of Permethrin (PER) and Piperonyl Butoxide (PBO) from Hand Surfaces Using Isopropyl Alcohol Dressing Sponges*
Report Date:	October 1, 2003
Testing Facility:	Toxcon Health Sciences Research Centre, Inc. 9607 - 41st Avenue Edmonton, Alberta Canada T6E 5X7
Analytical Facility:	EN-CAS Analytical Laboratories 2359 Farrington Point Drive Winston-Salem, NC 27107
Identifying Codes:	Toxcon Study No.: 01-013-PY01 EN-CAS Project No.: 01-0035

SPONSOR: Non-Dietary Exposure Task Force

EXECUTIVE SUMMARY:

This report reviews "*Determination of Removal Efficiency of Permethrin (PER) and Piperonyl Butoxide (PBO) from Hand Surfaces Using Isopropyl Alcohol Dressing Sponges*" submitted by the Non-Dietary Exposure Task Force. The purpose of the study was to measure the total amount of permethrin and piperonyl butoxide residues that can be removed from the hand surface, following application of a measured amount of a standard formulation to the hand.

Five test subjects participated in the study. The formulated product was diluted in isopropyl alcohol and 25 ·L was applied directly to the washed hands of the test subjects and allowed to dry for 30 minutes. Following the drying time, the hands of the subjects were then wiped with two dressing sponges wetted with isopropyl alcohol (IPA) to determine the removal efficiency of three concentrations of PER (0.771% ai) and PBO (0.741% ai) from the hand.

The total amount of residues removed from the hands by IPA were calculated by the study author for each hand of the test subjects. Residues were reported for PER and PBO at three different application rates. Nominal concentrations of 1.97 ug, 18.8 ug, and 59.2 ug PER, and associated concentrations of 1.72 ug, 16.9 ug and 56.0 ug of PBO were applied to the hands. Average PER residues removed from the test subjects' hands were 1.57 ug, 17.4 ug, and 52.7 ug. Average PBO residues removed from the test subjects' hands were 1.61 ug, 16.3 ug, and 49.5 ug. The residue values were 79.7% of the applied (1.97 ug nominal), 92.7% of the applied (18.8 ug nominal), and 89.0% of the applied (59.2 ug nominal) for PER residues. The residue values were 93.7% of the applied (1.72 ug nominal), 96.3% of the applied (16.9 ug nominal), and 88.4% of the applied (56.0 ug nominal) for PBO residues. The overall average recoveries were 87.1 ± 7.2% for PER and 92.8 ± 10.3% for PBO.

The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines were used to review the study. Overall, the majority of the procedures performed and the quality of the data generated in this study conformed to the criteria set forth in the protocol and guidelines. However, certain issues of concern were noted:

- The test product was not identified and no product label was provided.
- None of the test conditions (temperature, barometric pressure, ventilation) were reported.
- Information regarding the storage stability of the samples was not provided.
- The study author calculated residues based on the amount removed from the hand by the dressing sponges. The size of the test subjects' hands were not reported to determine the amount removed per unit surface area.

COMPLIANCE:
Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. The study report indicated that the study was conducted in compliance with EPA Good Laboratory Practices (GLPs) as defined in 40 CFR Part 160 with the following exception: information recorded on subject entry, exit and hand inspection forms was not entered and/or corrected according to GLP Regulations.

GUIDELINE OR PROTOCOL FOLLOWED:
The study was reviewed using OPPTS Test Guidelines Series 875, Occupational and Residential Exposure Test Guidelines, Group B: 875.2300. The study was conducted following EN-CAS and Toxcon Standard Operating Procedures and the protocol of the Non-Dietary Exposure Task Force (Toxcon Protocol No. 01-013-PY01). The study protocol was approved by study management in September 2001.

I. MATERIALS AND METHODS

A. Materials:

1. Test Material:

Formulation:	An unidentified pre-fill emulsion similar to that for an indoor fogger, developed by McLaughlin Gormley King Company (MGK); contains PER (0.771 % ai wt/wt) and PBO (0.741% ai wt/wt) as the active ingredients.
Lot/Batch # formulation:	0109-2 (test formulation); GLP 1474 (laboratory fortification samples)
Formulation guarantee:	Certificate of Analysis provided.
CAS #(s):	Permethrin: 52645-53-1 Piperonyl butoxide: 51-03-6
Other Relevant Information:	Toxcon ID No.: PY01 T009

2. Relevance of Test Material to Proposed Formulation(s):

PER and PBO are active ingredients used in formulated consumer products intended for use in residential buildings. The product used was a pre-fill emulsion similar to that of an indoor fogger formulation developed by McLaughlin Gormley King Company (MGK). The name and label for the test product was not provided with the study.

B. Study Design:

There were three amendments to and one deviation from the study protocol. The amendments were the following: 1) dressing sponges were used for removal of the test substance from the subject's hands rather than gauze sponges; 2) the Analytical Principal Investigator was Kathleen Faltynski and the permethrin reference substance lot number was 15365; 3) the sponsor representative and submitter for the Non-Dietary Exposure Task Force was David J. Carlson, Technical Director, effective December 5, 2002. The protocol deviation was the following: the diluted formulation solutions for application levels of 20 ug and 60 ug PER were not prepared on the day of use; for the high spike, 35 uL of solution was used instead of 25 uL; the dressing sponges wetted with IPA were placed inside the glass jars prior to spiking; and the Study Director did not supervise the hand wipe collection for one application day.

1. Site Description:

Test locations: Not applicable to the study. The test product was applied directly to the hands of five test subjects.

Meteorological Data: Not reported.

Ventilation/Air-Filtration: Not reported.

2. Surface(s) Monitored:

Room(s) Monitored: Not applicable to this study.

Room Size(s): Not applicable to this study.

Types of Surface(s): Hand surfaces (palms) of five test subjects.

Surface Characteristics: The subject's hands were washed with liquid Ivory soap, rinsed with tap water, and dried with a paper towel approximately 5 minutes before application of the formulated product.

Areas sprayed and sampled: The diluted formulated product was applied directly to the palms of the washed hands of the test subjects. The hands were sampled with dressing sponges to determine the removal efficiency.

Other products used: None

3. Physical State of Formulation as Applied : Liquid

4. Application Rates and Regimes:

Application Equipment: The diluted formulation was pipetted directly to the hands using a 25 uL or a combination of a 25 uL and 10 uL Wiretrol micropipette.

Application Regime: One application of the diluted product was applied to the washed palms of ten hands per concentration and allowed to dry for 30 minutes.

Application rate(s): The formulation was diluted with isopropyl alcohol to a nominal concentration of 1.97 ug, 18.8 ug, and 59.2 ug PER, and associated concentrations of 1.72 ug, 16.9 ug and 56.0 ug of PBO per 25 uL or 35 uL of isopropyl alcohol.

Equipment Calibration Procedures: Not applicable to this study.

Was total deposition measured? Not applicable to this study.

D. Sampling:

Surface Areas Sampled: The palms of five test subjects were sampled; however, the surface area measurement of their hands was not reported.

Replicates per sampling interval: Both hands of the five test subjects were sampled per concentration (10 total replicates).

Number of sampling intervals: There was one sampling interval that occurred approximately 30 minutes after the test substance was applied to the hands.

Method and Equipment: The hand wipe was conducted using two 4" x 4" 6-ply dressing sponges.

Sampling Procedure(s):

Deposition coupons - Not applicable to this study.

Hand residues - The removal of the test substance was conducted 30 minutes following application of the test substance. Five test subjects (10 hands) were used. The hand wipe consisted of wiping the palm of the hand with two 4" x 4" 6-ply dressing sponges. About 5 mL of IPA was added to each dressing sponge prior to use. The hand wipe procedure followed was Toxcon SOP M-023.

3. Sample Handling and Storage:

The dressing sponges from each hand were placed in glass separate pre-labeled 180 mL amber glass jars with Teflon lids and stored in the dark at less than -10°C until being shipped to the analytical laboratory. Sample storage and shipment were conducted according to Toxcon SOP Nos. G-022 *Storage of Test Samples and Analytical Extracts* and G-028 *Test Sample Distribution to a Contract Laboratory*. Samples were shipped to the analytical laboratory by airfreight with priority overnight delivery. Samples were shipped in an insulated cooler with dry ice.

IV. ANALYTICAL METHODOLOGIES

A. Extraction method:

Dressing sponges:Residues were extracted once from the dressing sponges by mechanical shaking for 30 minutes at room temperature with 70/30 hexanes/acetone. For PER and PBO test samples, a 1-mL aliquot of the final extract was transferred to an autoinjector vial containing dimethyldichlorosilane (DMDCS) which was added to help compensate for matrix effects. Field and laboratory controls and LOQ fortifications required concentration to bring the PER and PBO response into the linear region of the instrument calibration curves and to verify that the matrix background in the control samples was minimal. For PBO samples that required concentration, aliquots of extraction solvent were evaporated to dryness, and reconstituted in acetonitrile prior to analysis.

B. Detection methods:

A GC separation of the two isomers (cis and trans) of PER was achieved using a DB-5 column. Two distinct peaks were detected by electron capture detection (ECD), summed, and the total PER (cis plus trans) was quantitated on one curve. A GC with a mass selective detector (MSD) system fitted with a DB-1 column was used to quantitate the PBO residues. For quantitation of the concentrated controls, LOQ fortifications and field blanks, an alternate system for the detection of PBO was developed for the analysis of these low-level samples. For these samples, aliquots of the extraction solvent were carefully evaporated to dryness, reconstituted in acetonitrile and analyzed using an HPLC system equipped with a fluorescence detector (FD). A column switching system consisting of a Zorbax phenyl pre-column programmed to transfer only the pre-column eluant in the PBO retention time region to a Zorbax SB-C18 analytical column was used. A 60/40 acetonitrile/water eluant was used in the pre-column, while an 80/20 acetonitrile/water mixture was used in the C18 column. The fluorescence excitation and emission wavelengths monitored were 288 nm and 345 nm, respectively.

C. Method Validation:

EN-CAS Analytical Method No. ENC-2/01, entitled "*Analytical Method for the Determination of Permethrin (PER) and Piperonyl Butoxide (PBO) in/on Isopropanol-Moistened Dressing Sponges"* was successfully validated prior to initiation of this study. The validation results are reported in EN-CAS Project No. 01-0038, entitled *"Permethrin (PER) and Piperonyl Butoxide (PBO) Validation Study: The Determination of PER and PBO in/on 2- Propanol (IPA) Moistened Dressing Sponges"*. LOQs are reported for PER and PBO (see Table 1). The LOQs are based upon the lower limit of method validation. The actual LOQ fortification levels differ slightly due to variation in the percent active ingredient in individual formulations.

Table 1. Validated LOQ Values[1]		
Matrix	PER	PBO
Dressing Sponges	0.200 ug	0.173 ug

[1] LOQ values are based upon the lower limit of method validation (LLMV).

Instrument performance and calibration: Calibration solutions were prepared from the formulation by serial dilution with 70:30 hexanes:acetone to obtain PER and PBO calibration standards with the following concentrations: 0.005 ug/mL, 0.01 ug/mL, 0.02 ug/mL, 0.05 ug/mL, and 0.10 ug/mL. A 0.0025 ug/mL PBO standard was also prepared on 10/10/01. The GC response was determined using the prepared calibration standards to perform a linear regression analysis.

D. Quality Control:

Lab Recovery: To obtain recovery and method performance data, concurrent laboratory control dressing sponge samples were fortified with the test formulation. Samples were fortified at approximately 1X, 10X, 100X and 300X the LOQ. Results from the laboratory fortified samples are summarized in Table 2. The recovery of the low level spike for PER was 104.8% versus 100.2% at the high level. The recovery of the low level spike for PBO was 106.6% versus 93.2% at the high level. Overall average recoveries were 102.2 ± 6.57% for PER and 99.1 ± 9.15% for PBO.

Table 2. Summary of Concurrent Laboratory Fortification Recoveries

Matrix	Fortification Level (ug/sample)[1]		Measured Residue (ug/sample)		Percent Recovery (%)		Average Percent Recovery (%)		Overall Average Recovery (%)		Std. Dev.		% RSD	
	PER	PBO	PER	PBO	PER	PBO	PER	PBO	PER	PBO	PER	PBO	PER	PBO
Dressing sponge	0.20	0.173	0.231	0.188	115.5	108.7	104.8	106.6	102.2	99.1	6.57	9.15	6.43	9.23
			0.198	0.188	99.0	108.7								
			0.200	0.177	100.0	102.3								
	2.0	1.73	1.96	1.48	98.0	85.5	98.0	85.5						
	20	17.3	20.13	16.69	100.7	96.5	100.7	96.5						
	60	52.0	60.12	48.46	100.2	93.2	100.2	93.2						

[1] Fortification levels are 1X, 10X, 100X, 300X the LOQ.

Field Fortification: Diluted formulated product at the same levels as applied to the hands were prepared in triplicate by Toxcon and applied directly onto IPA moistened dressing sponges already placed into amber colored sample jars. Samples were fortified at approximately 10X, 100X, and 300X the LOQ. Field fortification results are summarized in Table 3. Overall average recoveries were 98.8 ± 6.06% for PER and 108.4 ± 10.4% for PBO.

Table 3. Summary of Field Fortification Recoveries														
Matrix	Fortification Level (ug/sample)[1]		Measured Residue (ug/sample)		Percent Recovery (%)		Average Percent Recovery (%)		Overall Average Recovery (%)		Std Dev.		%RSD	
	PER	PBO	PER	PBO	PER	PBO	PER	PBO	PER	PBO	PER	PBO	PER	PBO
Dressing Sponge	1.97	1.72	1.71	2.14	86.8	124	91.9	110	98.8	108	6.06	10.4	6.13	9.56
			1.84	1.92	93.4	112								
			1.88	1.62	95.4	94.2								
	18.8	16.9	18.9	19.6	101	116	102	107						
			20.0	18.9	106	112								
			18.7	15.5	99.5	91.7								
	59.2	56	59.5	58.0	101	104	103	109						
			61.1	63.0	103	113								
			61.5	61.7	104	110								

[1] Fortification levels are 10X, 100X and 300X the LOQ.

Control Samples: Each analytical set included one untreated laboratory control. Residues in all concurrent laboratory control samples were below the detection limit.

Storage Stability: Information regarding the storage stability of the samples was not provided.

V. RESULTS

Residues were reported for both PER and PBO. Field fortification recoveries were all >90%; therefore, the data did not need to be corrected. A summary of Versar's calculated residues are provided in Table 4.

A. Alpha Cellulose and Deposition of Formulation:

Not applicable to this study.

B. Hand Residues:

The total amount of residues removed from the hands by IPA were calculated by the study author for each hand of the test subjects. Residues were reported for PER and PBO at three different application rates. Nominal concentrations of 1.97 ug, 18.8 ug, and 59.2 ug PER, and associated concentrations of 1.72 ug, 16.9 ug and 56.0 ug of PBO were applied to the hands. Average PER residues removed from the test subjects' hands were 1.57 ug, 17.4 ug, and 52.7 ug. Average PBO residues removed from the test subjects' hands were 1.61 ug, 16.3 ug, and 49.5 ug. The residue values were 79.7% of the applied (1.97 ug nominal), 92.7% of the applied (18.8 ug nominal), and 89.0% of the applied (59.2 ug nominal) for PER residues. The residue values were 93.7% of the applied (1.72 ug nominal), 96.3% of the applied (16.9 ug nominal), and 88.4% of the applied (56.0 ug nominal) for PBO residues. The overall average recoveries were 87.1 ± 7.2% for PER and 92.8 ± 10.3% for PBO.

VI. CONCLUSION

Samples analyzed in this study were used to measure the removal of PER and PBO from bare hands to which known amounts of formulated product were applied. The study author calculated residues based on the amount removed from the hands by dressing sponges moistened with IPA. The recovered residue values were 79.7% of the applied (1.97 ug nominal), 92.7% of the applied (18.8 ug nominal), and 89.0% of the applied (59.2 ug nominal) for PER residues. The recovered residue values were 93.7% of the applied (1.72 ug nominal), 96.3% of the applied (16.9 ug nominal), and 88.4% of the applied (56.0 ug nominal) for PBO residues. The overall average recoveries were 87.1 ± 7.2% for PER and 92.8 ± 10.3% for PBO.

LIMITATIONS OF THE STUDY:

The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines were used to review the study. Overall, the majority of the procedures performed and the quality of the data generated in this study conformed to the criteria set forth in the protocol and guidelines. However, certain issues of concern were noted:

- The test product was not identified and no product label was provided.
- None of the test conditions (temperature, barometric pressure, ventilation) were reported.
- Information regarding the storage stability of the samples was not provided.
- The study author calculated residues based on the amount removed from the hand by the dressing sponges. The size of the test subjects' hands were not reported to determine the amount removed per unit surface area.

Table 5. Summary of PER and PBO Dressing Sponge Results from Hand Sampling

Sample	Nominal Application (ug)		Amount Recovered from Hands (ug)		Percent Recovered (%)		Average Amount Recovered (ug)		Average Percent Recovery (%)	
	PER	PBO	PER	PBO	PER	PBO	PER	PBO	PER	PBO
Dressing Sponges	1.97	1.72	1.74	1.48	88.3	86.0	1.57	1.61	79.7	93.7
			1.52	1.30	77.2	75.6				
			1.48	1.38	75.1	80.2				
			1.49	1.56	75.6	90.7				
			1.61	1.41	81.7	82.0				
			1.69	1.56	85.8	90.7				
			1.67	1.76	84.8	102.3				
			1.59	1.95	80.7	113.4				
			1.49	1.68	75.6	97.7				
			1.43	2.04	72.6	118.6				
	18.8	16.9	18.2	16.5	96.8	97.6	17.4	16.3	92.7	96.3
			17.4	15.4	92.6	91.1				
			15.9	17.4	84.6	103.0				
			16.4	14.5	87.2	85.8				
			17.7	17.1	94.1	101.2				
			17.0	15.6	90.4	92.3				
			17.9	17.8	95.2	105.3				
			17.5	14.3	93.1	84.6				
			18.5	17.1	98.4	101.2				
			17.7	17.0	94.1	100.6				
	59.2	56.0	51.4	44.0	86.8	78.6	52.7	49.5	89.0	88.4
			52.3	47.0	88.3	83.9				
			49.8	45.9	84.1	82.0				
			53.0	48.0	89.5	85.7				
			52.7	51.0	89.0	91.1				
			55.9	54.2	94.4	96.8				
			56.5	53.5	95.4	95.5				
			56.0	53.0	94.6	94.6				
			50.5	53.4	85.3	95.4				
			49.0	45.0	82.8	80.4				
Overall Mean					87.1	92.8				
Std. Dev.					7.2	10.3				

APPENDIX A

Compliance Checklist for "*Determination of Removal Efficiency of Permethrin (PER) and Piperonyl Butoxide (PBO) from Hand Surfaces Using Isopropyl Alcohol Dressing Sponges*"

Compliance Checklist for "Determination of Removal Efficiency of Permethrin (PER) and Piperonyl Butoxide (PBO) from Hand Surfaces Using Isopropyl Alcohol Dressing Sponges"

GUIDELINE 875.2300
INDOOR SURFACE RESIDUE DISSIPATION
POSTAPPLICATION

1. The test substance must be the typical end use product of the active ingredient. It is unclear whether this criterion was met. The test product was an unidentified product and no label was provided.

2. The production of metabolites, breakdown products, or the presence of contaminants of potential toxicologic concern, should be considered on a case-by-case basis. This criterion does not apply to this study. There was no mention of metabolites, breakdown products or other contaminants.

3. Indoor surface residue studies should be conducted under ambient conditions similar to those encountered during the intended use season, and should represent reasonable worst case conditions. This criterion does not apply to this study.

4. Ambient conditions (i.e., temperature, barometric pressure, ventilation) should be monitored. This criterion does not apply to this study.

5. The end use product should be applied by the application method recommended on the label. Information that verifies that the application equipment (e.g., sprayer) was properly calibrated should be included. This criterion does not apply to this study. Samples analyzed in this study were used to measure the removal efficiency of PER and PBO from bare hands that had been fortified with the formulated product.

6. The application rate used in the study should be provided and should be the maximum rate specified on the label. However, monitoring following application at a typical application rate is more appropriate in certain cases. This criterion does not apply to this study.

7. If multiple applications are made, the minimum allowable interval between applications should be used. This criterion was met.

8. Indoor surface residue (ISR) data should be collected from several different types of media (e.g., carpeting, hard surface flooring, counter tops, or other relevant materials). This criterion does not apply to this study. The objective of this study was to measure the removal efficiency of PER and PBO from bare hands that had been fortified with the formulated product.

9. Sampling should be sufficient to characterize the dissipation mechanisms of the compound (e.g., three half-lives or 72 hours after application, unless the compound has been found to fully dissipate in less time; for more persistent pesticides, longer sampling periods may be necessary). Sampling intervals may be relatively short in the beginning and lengthen as the study progresses. Background samples should be collected before application of the test substance occurs. This criterion does not apply to this study.

10. Triplicate, randomly collected samples should be collected at each sampling interval for each surface type. This criterion was met.

11. Samples should be collected using a suitable methodology (e.g., California Cloth Roller, Polyurethane Roller, Drag Sled, Coupons, Wipe Samples, Hand Press, vacuum cleaners for dust and debris, etc.) for indoor surfaces. This criterion was met.

12. Surface sampling should be conducted in conjunction with air sampling. Enough duplicate air samples should be taken in a room to establish a dissipation curve. This criterion does not apply to this study. The test substance was not sprayed. It was applied by pipette directly to the test subject's hands.

13. Samples should be stored in a manner that will minimize deterioration and loss of analytes between collection and analysis. Information on storage stability should be provided. This criterion was not met. Information regarding storage stability of the samples was not provided.

14. Validated analytical methods of sufficient sensitivity are needed. Information on method efficiency (residue recovery), and limit of quantitation (LOQ) should be provided. This criterion was met.

15. Information on recovery samples must be included in the study report. A complete set of field recoveries should consist of at least one blank control sample and three or more each of a low-level and high-level fortification. These fortifications should be in the range of anticipated residue levels in the field study. This criterion was met.

16. Raw residue data must be corrected if appropriate recovery values are less than 90 percent. This criterion was met. Field fortification recoveries were all >90%; therefore, data correction was not required.

17. Indoor surface residues should be reported as mg per m^2 or cm^2 of surface sampled. Distributional data should be reported, to the extent possible. This criterion was not met. However, the known concentration of the formulated product was applied directly to the test subject's hands; therefore, the size of the test subject's hands may not be a factor.

18. Reported residue dissipation data in conjunction with toxicity data should be sufficient to support the determination of a reentry interval. This criterion does not apply to this study.